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Amendments to the Claims

1-9. (Cancelled)

10. (Previously presented) A monolayer film formed from a mucoadhesive composition, which comprises

i. one or more ingredients selected from the group consisting of water-soluble polymers and water-dispersible polymers,

ii. one or more pharmaceutically active agents deliverable via a mucous membrane,

iii. one or more flavoring agents,

iv. one or more sweeteners, and

v. a mixture of at least two non-ionic surfactants, said mixture comprising a first component which is a polyoxyethylene sorbitan fatty acid ester or a α-hydroxy-ω-hydroxypoly(oxyethylene)-poly(oxypropylene)poly(oxyethylene) block copolymer, and a second component which is a polyoxyethylene alkyl ether or a polyoxyethylene castor oil derivative; and

wherein said film is able to be adhered to an oral cavity and immediately softens after application to mucosal tissue, and said film effects the transmucosal delivery of said one or more pharmaceutically active agents when adhered to said oral cavity.

11. (Previously presented) A monolayer film according to claim 10 which further comprises one or more flavor enhancing agents.

12. (Previously presented) A monolayer film according to claim 10 which further comprises one or more colorants.

13. (Previously presented) A monolayer film according to claim 10 having a dry thickness between 5 and 200 μm.

14. (Previously presented) A monolayer film according to claim 10 which further comprises one or more flavor enhancing agents and one or more colorants.

15. (Previously presented) A monolayer film according to claim 14 having a dry thickness between 5 and 200 μm.

16. (Previously presented) A monolayer film according to claim 11 having a dry thickness between 5 and 200 μm.

17. (Previously presented) A monolayer film according to claim 12 having a dry thickness between 5 and 200 μm.

18. (Previously presented) A monolayer film according to claim 10 wherein the water-soluble polymer is selected from the group consisting of a water-soluble cellulose derivative, hydroxypropyl methylcellulose and xanthan gum.

19. (Previously presented) A monolayer film according to claim 10 wherein the mixture of surfactants comprises a polyoxyethylene sorbitan fatty acid ester and a polyethylene alkyl ether.

20. (Previously presented) A monolayer film according to claim 10 wherein the pharmaceutically active agent is selected from the group consisting of nicotine and nicotine salts.

21. (Previously presented) A monolayer film according to claim 10 wherein the flavoring agent is menthol and/or mint flavor.

22. (Previously presented) A monolayer film according to claim 11 wherein the flavor enhancing agent is tartaric acid.

23. (Previously presented) A monolayer film according to claim 10 wherein the sweetener is at least one member selected from the group consisting of aspartame and sorbitol.

24. (Previously presented) A monolayer film formed from a mucoadhesive composition, which comprises

i. a combination of water-soluble polymers, said combination comprising one or more substances selected from the group consisting of water-soluble cellulose derivatives and further comprising one or more water-soluble polymers selected from the group consisting of polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, natural gums, water-dispersible polyacrylates and carboxyvinyl copolymers,

ii. one or more pharmaceutically active agents selected from nicotine salts,

iii. one or more flavoring agents selected from the group consisting of menthol and mint flavor,

iv. one or more sweeteners selected from the group consisting of aspartame and sorbitol, and

v. tartaric acid as a flavor enhancing agent,

wherein said film is able to be adhered to an oral cavity and immediately softens after application to mucosal tissue.

25. (Previously presented) A monolayer film according to claim 24 having a dry film thickness about between 5 and 200 μm.

26. (Previously presented) A monolayer film according to claim 24 wherein the concentration of water-soluble polymer is between 20 and 75% (w/w) and the amount of the pharmaceutically active agent is between 0.01 and 20% (w/w).

27. (Previously presented) A monolayer film according to claim 25 wherein the concentration of water-soluble polymer is between 20 and 75% (w/w) and the amount of the pharmaceutically active agent is between 0.01 and 20% (w/w).

28. (Previously presented) A composition applicable to the oral cavity, for releasing active substances in the oral cavity, wherein the composition comprises as essential components polyvinyl pyrrolidone and hydroxypropylmethyl cellulose, and the active substance, nicotine, which is present in the form of a salt and wherein said composition exhibits instant wettability which causes the composition to soften immediately after application to the oral mucosa, followed by rapid dissolution or disintegration of the composition, and said composition is a film that is orally applicable and that has a thickness of not more than 70 μm.

29. (Previously presented) A composition according to claim 28, wherein the thickness of said film is between 5 and 70 μm.

30. (Cancelled)

31. (Previously presented) A composition according to claim 28, further comprising at least one water-soluble or water-dispersible polymer selected from the group consisting of water-soluble cellulose derivatives, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, natural gums, water-dispersible polyacrylates, and mixtures of the aforementioned polymers.

32. (Cancelled)

33. (Previously presented) A composition according to claim 28, wherein the concentration of the polyvinyl pyrrolidone and hydroxypropylmethyl cellulose lies between 20 and 75%-wt..

34. (Previously presented) A composition according to claim 28, further comprising at least one polyalcohol.

35. (Previously presented) A composition according to claim 34, wherein the proportion of the polyalcohol amounts to 0.1 to 5 %-wt. of the dry composition.

36. (Previously presented) A composition according to claim 28, further comprising at least one surfactant, the total concentration of surfactant(s) being in the range of 0.1 to 5 %-wt.

37. (Currently amended) A composition according to claim 28, further comprising a mixture of nonionic surfactants, said mixture consisting of two components, the first component being a polyoxyethylene sorbitan fatty acid ester or a ~~α-hydro-ω-hydroxypoly(oxyethylene)-poly(oxypropylene)poly(oxyethylene)~~ α-hydroxy-ω-hydroxypoly(oxyethylene)-poly(oxypropylene)poly(oxyethylene) block copolymer, and the second component being a polyoxyethylene alkyl ether or a polyoxyethylene castor oil derivative, wherein the ratio between the first and second component of the binary surfactant mixture is maintained between 1:10 and 1:1 preferably between 1:5 and 1:3, and wherein the total concentration of surfactants is in the range of 0.1 to 5%-wt.

38. (Previously presented) A composition according to claim 28, wherein the amount of active substance incorporated into the composition is between 0.01 and 20 %-wt.

39. (Previously presented) A composition according to claim 28, further comprising one or more ingredients selected from the group of flavors, flavor enhancers and fragrances.

40. (Previously presented) A composition according to claim 28, further comprising a cosmetically active ingredient that is selected from the group consisting of breath freshening compounds, flavors used for oral hygiene, fragrances used for oral hygiene, active agents used for oral cleansing, and active agents used for dental cleansing.

41. (Withdrawn) A process for the manufacture of an orally applicable film applicable for releasing active substances in the oral cavity, said process comprising the steps of:

(a) dissolving or dispersing, while stirring, at least one polymer selected from the group of water-soluble or water-dispersible polymers, to form a solution or dispersion;

(b) adding the active substance, nicotine;

(c) coating this solution or dispersion onto a carrier material which has a surface tension which prevents the solution or dispersion from being soaked into the carrier material;

(d) drying the solution or dispersion to form said film;

(e) peeling the film off the carrier material; and

(f) cutting the film into pieces of suitable size.

42. (Withdrawn) A process according to claim 41, wherein nicotine is added in the form of a salt, preferably as nicotine salicylate.

43. (Withdrawn) A process according to claim 41, wherein said polymer(s) is/are selected from the group consisting of: water-soluble cellulose derivatives, in particular hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose; and polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol; and natural gums, in particular xanthane gum, tragacantha, guar gum, acacia gum, arabic gum; water-dispersible polyacrylates, in particular polyacrylic acid, methylmethacrylate copolymer,

carboxyvinyl copolymers; and mixtures of the aforementioned polymers.

44. (Withdrawn) A process according to claim 41, wherein said solution or dispersion further contains one or more ingredients selected from the group of flavors, flavor enhancers, fragrances, breath freshening compounds, flavors used for oral hygiene, fragrances used for oral hygiene, active agents used for oral cleansing, and active agents used for dental cleansing.

45. (Withdrawn) A method for administering a pharmaceutically active agent to a person, wherein said agent is nicotine, said method comprising the steps of:

(a) applying a film into the oral cavity of said person, said film containing said agent and exhibiting instant wettability;

(b) releasing said agent into said oral cavity by dissolution or disintegration of said film in the oral cavity.

46. (Withdrawn) A method according claim 45, wherein said nicotine is present as a nicotine salt, preferably nicotine salicylate.

47. (Withdrawn) A method according to claim 45, wherein said film comprises as essential component(s) at least one water-soluble or water-dispersible polymer.

48. (Withdrawn) A method according to claim 47, wherein said polymer(s) is/are selected from the group consisting of: water-soluble cellulose derivatives, in particular hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose; and polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol; and natural gums, in particular xanthane gum, tragacantha, guar gum, acacia gum, arabic gum; water-dispersible polyacrylates, in particular polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl copolymers; and mixtures of the aforementioned polymers; the combination of polyvinyl pyrrolidone and hydroxypropylmethyl cellulose being particularly preferred.

49. (Withdrawn) A method according claim 45, wherein said nicotine is administered to the oral mucosa.

50. (Withdrawn) A method according to claim 45, wherein said film has a thickness which is between 5 and 200 μm, preferably between 5 and 70 μm.

51. (Withdrawn) A method according to claim 45, wherein said film further contains one or more ingredients selected from the group of flavors, flavor enhancers, fragrances, breath freshening compounds, flavors used for oral hygiene, fragrances used for oral hygiene, active agents used for oral cleansing, and active agents used for dental cleansing.

52. (Previously presented) A composition according to claim 28, wherein the salt is nicotine salicylate.

53. (Previously presented) A composition according to claim 31, wherein the water-soluble cellulose derivative is hydroxyethyl cellulose or hydroxypropyl cellulose; the natural gum is xanthane gum, tragacantha, guar gum, acacia gum or arabic gum; and the water-dispersible polyacrylate is polyacrylic acid, methylmethacrylate copolymer or a carboxyvinyl copolymer.

54. (Previously presented) A composition according to claim 33, wherein the concentration of the polyvinyl pyrrolidone and hydroxypropylmethyl cellulose is between 50 and 75%-wt..

55. (Previously presented) A composition according to claim 34, wherein the polyalcohol is selected from the group consisting of glycerol, polyethylene glycol, propylene glycol, and glycerol monoesters with fatty acids.

56. (Previously presented) A composition according to claim 39, wherein the one or more ingredients are selected from the group consisting of menthol, lemon mint flavor, peppermint flavor, herb mint flavor, aspartame and caramel.

57. (Previously presented) A monolayer film according to claim 10, wherein said pharmaceutically active agent(s) is or are selected from the group consisting of hypnotics, sedatives, antiepileptics, awakening agents, psychoneurotropic agents, neuromuscular blocking agents, antispasmodic agents, antihistaminics, antiallergics, cardiotonics, antiarrhythmics, diuretics, hypotensives, vasopressors, antitussive expectorants, thyroid hormones, sexual hormones, antidiabetics, antitumor agents, antibiotics, chemotherapeutics, and narcotics.

58. (Previously presented) A monolayer film according to claim 10, wherein said ingredients selected from the group consisting of water-soluble polymers and water-dispersible polymers comprise a mixture of polyvinylpyrrolidone, polyethylene glycol and hydroxypropyl-methyl cellulose.

59. (Previously presented) A composition according to claim 28, further comprising caramel.

60. (Previously presented) A composition according to claim 59, wherein said salt is nicotine salicylate.

61. (Previously presented) A composition according to claim 24, wherein said salt is nicotine salicylate.